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EXAMINER

ROSE, SHEP K

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 02/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840844

Applicant(s)

MONTGOMERY

Examiner

S. ROSE

Group Art Unit

614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1 3627 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 3627 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1 3627 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 to 16 are rejected under 35 U.S.C. 102(b) as being anticipated by each of:

Makagawa et al U.S. 3901819 (8/75) describing anhydrous dry granules of triacetin (glyceryl triacetate) ("GTA") with sodium percarbonate or hydrogen peroxide, surfactants, chelating agents. See: claims 4, 5, 13, and 15, example 3, granules, column 2, lines 30 to 52.

Jones U.S. 3956159 (5/76), anhydrous liquid bleach comprising "GTA" (glyceryl triacetate), (claim 1) pH buffer (claim 12), column 4, lines 21 to 37, chelating agents 1 column 4, lines 1 to 20).

Green et al U.S. 4,772,412 (9/88), glyceryl triacetate "GTA", (column 9, line 26) in non-aqueous liquid carriers (claim 1) with sodium perborate, surfactants and chelating See: column 6, lines 1 to 43.

Barnes U.S. 4981606 (1/91), glyceryl triacetate, ("GTA") with sodium perborate, surfactants, sequestrates, etc. See: col. 2, lines 58-60, column 8, line 11 is anhydrous liquids.

Kong et al U.S. 5505740 (4/96), describe glyceryl triacetate, ("GTA"), Table 3, column 18, with hydrogen peroxide source in encapsulated, coated dry tablets, at columns 11 and 12, with surfactants, buffers, optimized to alkaline pH.

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Composition claims 1 and 3 to 16 differ from these prior bleaching compositions (dry granules or anhydrous liquids) comprising glyceryl triacetate, an encompassed acetic acid ester of glycerin, (claim 3 Markush group) and encompassed species of peroxide sources (claim 4 Markush group) described with anhydrous dry granule or liquid carriers (claim 8 Markush group); thickening agents (claim 10 Markush group); buffer (claim 12 Markush group); surfactant (claim 14 Markush group); and chelating agents (claim 16 Markush group); only by a statement of intended use in the preamble of these otherwise old bleach compositions, herein intended as an oral care composition for whitening teeth. They inherently function to bleach laundry, as taught by this prior art. A statement of intended new use cannot impart patentable novelty on otherwise old composition. The only oral care components not found in the old bleach compositions are in dependent claim 17 "flavorants and sweeteners" but both can be found in an encompassed species of oral care compositions, namely denture cleansers, for whitening an encompassed species of teeth, namely false teeth.

The only carriers recited in dependent claim 8 not found in prior art bleach compositions are the chewing gum and dental floss species.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17 to 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al or McLaughlin (details herein below) taken with anyone of each of Nakagawa et al, Jones Green et al, Barnes, and Sanderson et al (details above), the prior bleach art describing GTA and peroxide precursors in anhydrous systems, as noted above. Gaffar et al and McLaughlin describe prior art dual component tooth whitening systems with flavors or sweeteners keeping hydrogen peroxide (or its precursors) in one component, neither mentioning applicant's acetic esters of glycerin to be among their described species of peroxide activators/catalysts, but the prior bleach art, as noted above, does describe this benefit or property for "GTA", glyceryl triacetate, with encompassed species of hydrogen peroxide precursors. It would be entirely in accordance with the prior art concepts of McLaughlin and Gaffar et al for tooth whitening systems to replace their explicitly described species of peroxide activators/catalysts with other known species of peroxide activators/catalysts, including the "GTA" (glyceryl triacetate), ("triacetin") species of peroxide activator/catalyst described as such by each of Nakagawa et al. Jones, Green et al, Barnes and Sanderson et al, and to thereby keep it apart from the peroxide or peroxide precursor.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19 to 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 of U.S. Patent No. 6,221,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope to substantially the same inventions.

This application is a continuation, and not a divisional application filed as a result of any USPTO requirement under 35 USC 121 to restrict the claims of the parent application Serial No. 09/196403, filed November 19, 1998, now U.S. Patent No. 6,221,341, whose two claims are drawn to the same method for whitening teeth with "GTA" (glyceryl triacetate) and the same encompassed species of hydrogen peroxide as presented in method of whitening claims 19 to 27 herein, presenting a clear issue of obviousness-type double patenting.

Claims 19 to 27 are rejected under the judicially created doctrine of double patenting over claims 1, 2 of U. S. Patent No. 6,221,341 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: as noted above.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Montgomery et al U.S. 6162055 claim tooth-whitening methods, which in claims 8 to 12 therein employ peroxides like hydrogen peroxide or peroxyacids like peroxy acetic acid. Column 9, lines 2 to 13 contemplate "GTA", glyceryl triacetate, a peroxy acid precursor may be in a separate phase from (page 8, lines 57 to 66) an oxidizing phase including, but not limited to, hydrogen peroxide, carbamide peroxide, alkali metal peroxides, and peroxyacetic acid.

Montgomery U.S. 5922307 (claims 1, 47) claims a tooth surface bleaching method comprising hydrogen peroxide 10% water, a thickening agent, on alkaline pH adjusting agent, and a calcium-chelating agent, with a bleaching pH of 6.0 to 10.0.

Montgomery U.S. 5908614 (claim 1 to 9), claims 1, 2 and 5 to dry non-aqueous substantially water free chewing gum, pH 4 to 6.5, and coated sodium percarbonate

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hydrogen peroxide precursor, and method claims 4, 7, and 9 to their oral administration to the oral cavity of an animal.

Claims 19 to 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 to 12 of U.S. Patent No. 6,221,341 in view of Nakagawa et al, Jones, Green et al, Barnes and/or Sanderson et al (details above) in view of anyone of which it is obvious to one of ordinary skill in the art, that the addition of "GTA" (glyceryl triacetate) to expectedly boost the peroxide or peroxide precursor would not only be motivated, but there would also be a reasonable likelihood of success, especially in the absence of evidence to the contrary.

Claims 19 to 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 7 of U.S. Patent No. 5,922,307 in view of Nakagawa et al, Jones, Green et al, Barnes and/or Sanderson et al (details above) in view of anyone of which motivation is evident to include "GTA" (glyceryl triacetate) for its expected "boost" to the activity of the hydrogen peroxide or hydrogen peroxide precursor, with a reasonable likelihood of success, especially in the absence of evidence to the contrary.

Claims 1, 3, 4, 5, 7, 8, 11, 12, 17, 19, to 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 7, 9 of U.S. Patent No. 5,908,614 in view of Nakagawa et al, Jones, Green et al, Barnes and/or Sanderson et al (details above) in view of anyone of which motivation is evident to include "GTA" (glyceryl triacetate) in the anhydrous chewing gum, for its

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expected "boost" to the activity of the coated sodium percarbonate hydrogen peroxide precursor especially in the absence of evidence to the contrary.

From the teachings of the "GTA" peroxide bleach references, it was apparent that one of ordinary skill in the art would not only be motivated, but would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

There is no allowable generic claim and plural species have been presented. Claims 1 and 2 to 18 are generic to compositions comprising a plurality of disclosed patentably distinct species comprising

One ultimate disclosed species of:

- (a) A peroxide source selected from one recited in claim 4 and (A-2) an acetic acid ester of glycerin from claim 3;
- (b) one ultimate disclosed anhydrous carrier from one of those recited in claim 8
- (c) (If further elected) one or more further thickeners, buffers surfactants chelating components from those recited in claims 10, 12, 14, and 16 respectively
- (d) (If further elected) a two component systems with glyceryl acetate separated from an aqueous hydrogen peroxide component recited in claim 18.
- (e) (If further elected) an additional flavorant or sweetener as recited in claim 17

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Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, of each, even though this requirement is traversed. If this application is filed under Rule 371, the legal authority is PCT Rule 13.2, Annex B, Part 1 (f) "Markush Practice"; PCT Rule 13 and 35

U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under U.S.C. § 103 (of) the other invention.

Election of species is required per MPEP § 803, 809.02 (d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USOQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an Office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each species (as noted above) is capable of independent manufacture, use and sale, with the other components of the claimed formulations.

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Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Rose/LR

February 12, 2002



SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200